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APPLICATION NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTORNEY DOCKET NO.
08/425,022	04/19/95	BERTENSHAW	S 5400/2

G D SEARLE AND COMPANY
CORPORATE PATENT LAW DEPARTMENT
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12M2/1105

EXAMINER

DENTZ, B

ART UNIT	PAPER NUMBER
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1203

DATE MAILED: 11/05/96

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

OFFICE ACTION SUMMARY

- ☐ Responsive to communication(s) filed on _____
- ☐ This action is FINAL.
- ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s) ~~on thirty days~~, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

- ☒ Claim(s) 47-62 is/are pending in the application.
- Of the above, claim(s) _____ is/are withdrawn from consideration.
- ☐ Claim(s) _____ is/are allowed.
- ☒ Claim(s) 47-62 is/are rejected.
- ☐ Claim(s) _____ is/are objected to.
- ☐ Claims _____ are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- ☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- ☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
- ☐ received.
- ☐ received in Application No. (Series Code/Serial Number) _____
- ☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

- ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- ☒ Notice of Reference Cited, PTO-892
- ☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 7
- ☐ Interview Summary, PTO-413
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Notice of Informal Patent Application, PTO-152

- SEE OFFICE ACTION ON THE FOLLOWING PAGES -

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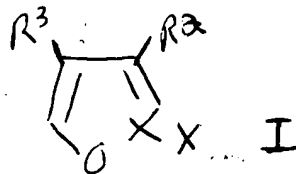
Applicants have broadened the claims after arguing the art rejection. It is the Examiners opinion that the art rejection is valid.

Further in the interests of effective prosecution the proviso of dependent claim 42 which was in canceled original independent claim 35 to the effect that one of the R^2 and R^3 substituents is substituted with lower alkylsulfinyl or sulfamyl will be read into instant independent claims 47, 49, 51, 53, 57, 59 and 61 to replace the proviso which is actually in the claims.

This interpretation is also justified by the principle of election of subject matter to be examined based on the initial elected invention.

Claims 47-52 and 55-60 are rejected under 35 U.S.C. 112 paragraph 1 as not being enabled.

The specification does not enable one of ordinary skill in the art to synthesize 2-hydroxyfurans, i.e. compounds of the formula wherein X is -OH.



Two classic references in the field of furans are Elderfields-Heterocyclic Compounds Vol. 1, Chapter 4. (1950). and "The Furans" by Dunlop and Peters (1953). Another reference dealing with "2-hydroxyfurans" is Hornfeldt, Svensk Kemiisk Tidskrift p. 343-356.

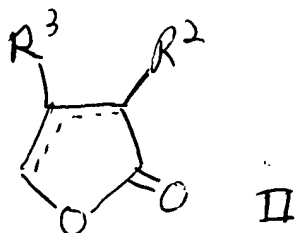
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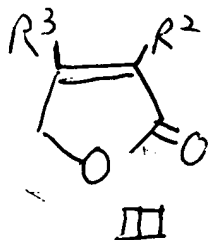
The first sentence in each [^] section dealing with the subject of "furanols" or as they are also called "hydroxy-furans" is indicative of the great instability, difficulty of synthesis and difficulty of characterization of substances which might be expected to possess their structure.

See Elderfield at pg. 177 first sentence and pg. 170 and pg.

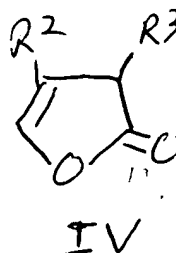
173, first complete paragraph of "The Furans". See p. 343-346, especially p. 343, col. 2 penultimate paragraph of the last reference.
Further claims 47-50 and 55-58 recite compounds and their pharmaceutical compositions of the formula.



This structure includes



and



The synthesis of a compound of formula III is disclosed by Scheme IV and Ex. 13. Thus these compounds are enabled. (Note

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that in the specification they are disclosed only as intermediates).

However compounds of formula IV are not enabled or described. There is no mention of them in the specification. Note that 2-hydroxyfuran (meaning and identity in doubt) are considered as a non-preferred tautomeric form of lactone IV. Note that there is apparently another highly unstable entity also referred to as 2-hydroxy-furan. Thus the Examiner is taking the position that applicants schematic depiction of the instant 2-hydroxyfurans doesn't provide support for lactone IV. Further said instant depiction most assuredly provides no support for lactone III.

Thus claims 47-50 and 55-58 are rejected under 35 USC 112, first paragraph since the specification fails to describe the lactones IV. With respect to claims 55-58 the embodiment wherein III is the active ingredient is also not described.

Claims 47-50 and 55-58 are rejected under 35 USC 112, paragraph 2 for failing to particularly point out the invention with regard to lactones IV and with respect to claims 55-58 for III also for the reasons given above.

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Claims 47-50 and 55-58 are rejected under 35 U.S.C. § 102(e) as anticipated by or, in the alternative, under 35 U.S.C. § 103 as obvious over DUcharme et al. for the reason of record in Paper No. 8.

It is the Examiner's position that the instant alpha-beta butenolides do not find effective support in any of applicants cases while Ducharme et al. U.S. Patent 5,474,995 has an effective date of June 24, 1993 for this material.

Since new 35 USC 112 rejections are made this action is not final.

Claims 53 and 54 are rejected under 35 USC 112 as not particularly pointing out the invention originally claimed since the new replacement proviso substantially broadens the claims.

Any inquiry concerning this communication should be directed to Examiner Dentz at telephone number (703) 308-4544.

Dentz - C. Williams

October 29, 1996

B. Dentz
BERNARD DENTZ
PRIMARY EXAMINER
GROUP 1200